116. Answering Defendants state that the potential effects of Celebrex® were and are adequately described in their FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Answering Defendants deny that the warning given to prescribers and users of Celebrex® were defective. Except as admitted herein, Answering Defendants deny the allegations contained in this Paragraph as they relate to Answering Defendants.

117. Answering Defendants admit that they have such duties as are imposed by applicable law, but deny that they breached any such duty. Except as admitted herein, Answering Defendants deny the allegations contained in this Paragraph as they relate to Answering Defendants.

118. Answering Defendants deny that Celebrex® caused Plaintiff and/or decedent any harm and deny that Plaintiff is entitled to any damages. Answering Defendants deny the remaining allegations contained in this Paragraph as they relate to Answering Defendants.

ANSWERING:
COUNT IV – FRAUD AND FALSE ADVERTISING
(Against Merck and Pfizer)

119. Answering Defendants incorporate their responses to Paragraphs 1-118 as if set forth fully herein.

120. Answering Defendants admit that they have such duties as are imposed by applicable law, but deny that they breached any such duty. Except as admitted herein, Answering Defendants deny the allegations contained in this Paragraph as they relate to Answering Defendants.

121. Answering Defendants state that Celebrex® was and is safe and effective when used in accordance with their FDA-approved prescribing information. Answering Defendants deny misrepresenting or concealing material facts regarding the safety or effectiveness of Celebrex®. Except as admitted herein, Answering Defendants deny the allegations contained in this Paragraph as they relate to Answering Defendants.

122. Answering Defendants state that Celebrex® was and is safe and effective when used in accordance with their FDA-approved prescribing information. Answering Defendants state that the potential effects of Celebrex® were and are adequately described in their FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Except as admitted herein, Answering Defendants deny the allegations contained in this Paragraph as they relate to Answering Defendants.

123. Answering Defendants deny the allegations contained in this Paragraph as they relate to Answering Defendants.

124. Answering Defendants state that Celebrex® was and is safe and effective when used in accordance with their FDA-approved prescribing information. Answering Defendants deny that Celebrex® was unsafe. Except as admitted herein, Answering Defendants deny the allegations contained in this Paragraph as they relate to Answering Defendants.

125. Answering Defendants state that Celebrex® was and is safe and effective when used in accordance with their FDA-approved prescribing information. Answering Defendants deny making misrepresentation regarding Celebrex®. Answering Defendants also deny that Celebrex® was defective or dangerous. Except as admitted herein, Answering Defendants deny the allegations contained in this Paragraph as they relate to Answering Defendants.

126. Answering Defendants state that Celebrex® was and is safe and effective when used in accordance with their FDA-approved prescribing information. Answering Defendants deny making misrepresentations or concealments regarding Celebrex®. Except as admitted herein, Answering Defendants deny the allegations contained in this Paragraph, including and all of its subparts, as they relate to Answering Defendants.

127. Answering Defendants deny making misrepresentations or concealments. Answering Defendants deny the allegations contained in this Paragraph as they relate to Answering Defendants.

128. Answering Defendants deny the allegations contained in this Paragraph as they relate to Answering Defendants. Answering Defendants state that Celebrex® was and is safe and effective when used in accordance with their FDA-approved prescribing information. Answering Defendants state that the potential effects of Celebrex® were and are adequately described in their FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Answering Defendants deny making fraudulent misrepresentations.

129. Answering Defendants deny the allegations contained in this Paragraph as they relate to Answering Defendants.

130. Answering Defendants have insufficient information or knowledge to form a belief as to the truth of the allegations regarding Decedent's knowledge and therefore deny the same. Answering Defendants deny making misrepresentations and concealments. Answering Defendants deny the remaining allegations in this Paragraph as they relate to Answering Defendants.

131. Answering Defendants have insufficient information or knowledge to form a belief as to the truth of the allegations regarding Decedent's reliance and therefore deny the same. Answering Defendants state that the potential effects of Celebrex® were and are adequately described in their FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Answering Defendants deny making misrepresentations or concealments. Except as admitted herein, Answering Defendants deny the allegations contained in this Paragraph as they relate to Answering Defendants.

132. Answering Defendants deny making misrepresentations and concealments. Answering Defendants deny the allegations contained in this Paragraph as they relate to Answering Defendants.

133. Answering Defendants state that during certain period(s) of time, Pfizer co-promoted and marketed the prescription drug Celebrex® in the United States for the indications set forth in the FDA-approved package inserts and as permitted by law. Answering Defendants also state that Celebrex® was and is safe and effective when used in accordance with their FDA-approved prescribing information. Further, Answering Defendants state that the potential effects of Celebrex® were and are adequately described in their FDA-approved prescribing information, which was at all

times adequate and comported with applicable standards of care and law. Except as admitted herein, Answering Defendants deny the allegations contained in this Paragraph as they relate to Answering Defendants.

134. Answering Defendants state that Celebrex® was and is safe and effective when used in accordance with their FDA-approved prescribing information. Except as admitted herein, Answering Defendants deny the allegations contained in this Paragraph as they relate to Answering Defendants.

135. Answering Defendants state that this Paragraph contains legal conclusions to which no response is required. To the extent a response is deemed required, Answering Defendants deny making misrepresentations and concealments. Answering Defendants deny the remaining allegations contained in this Paragraph as they relate to Answering Defendants.

136. Answering Defendants deny that Celebrex® caused Plaintiff and/or decedent any harm and deny that Plaintiff is entitled to any damages. Answering Defendants deny the remaining allegations contained in this Paragraph as they relate to Answering Defendants.

ANSWERING:
COUNT V – MISREPRESENTATION BY SELLER OF CHATTEL
(Against Merck and Pfizer)
Restatement of Torts (Second) § 402B
Restatement of Torts (Third): Prod. Liab. § 9

137. Answering Defendants incorporate their responses to Paragraphs 1-136 as if set forth fully herein.

138. Answering Defendants state that, during certain period(s) of time, Pfizer co-promoted and marketed the prescription drug Celebrex® in the United States for the indications set forth in the FDA-approved package inserts and as permitted by law. Except as admitted herein, Answering Defendants deny the allegations contained in this Paragraph as they relate to Answering Defendants.

139. Answering Defendants state that Celebrex® was and is safe and effective when used in accordance with their FDA-approved prescribing information. Except as admitted herein, Answering Defendants deny the allegations contained in this Paragraph as they relate to Answering Defendants.

140. Answering Defendants state that the potential effects of Celebrex® were and are adequately described in their FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Answering Defendants deny making misrepresentations. Answering Defendants state that Celebrex® was and is safe and effective when used in accordance with their FDA-approved prescribing information.

141. Answering Defendants deny that Celebrex® caused Plaintiff and/or decedent any harm and deny that Plaintiff is entitled to any damages. Answering Defendants deny the remaining allegations contained in this Paragraph as they relate to Answering Defendants.

ANSWERING:
COUNT VI – BREACH OF EXPRESS AND IMPLIED WARRANTY
(Against Merck and Pfizer)

142. Answering Defendants incorporate their responses to Paragraphs 1-141 as if set forth fully herein.

143. Answering Defendants state that Celebrex® was and is safe and effective when used in accordance with their FDA-approved prescribing information. Except as admitted herein, Answering Defendants deny the allegations contained in this Paragraph as they relate to Answering Defendants.

144. Answering Defendants deny the allegations contained in this Paragraph, including all of its subparts, as they relate to Answering Defendants.

145. Answering Defendants deny the allegations contained in this Paragraph as they relate to Answering Defendants.

146. Answering Defendants state that Celebrex® was and is safe and effective when used in accordance with their FDA-approved prescribing information. Except as admitted herein, Answering Defendants deny the allegations contained in this Paragraph as they relate to Answering Defendants.

147. Answering Defendants state that Celebrex® was and is safe and effective when used in accordance with their FDA-approved prescribing information. Answering Defendants also state that the potential effects of Celebrex® were and are adequately described in their FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Except as admitted herein, Answering Defendants deny the allegations contained in this Paragraph as they relate to Answering Defendants.

148. Answering Defendants state that Celebrex® was and is safe and effective when used in accordance with their FDA-approved prescribing information. Answering Defendants also state that the potential effects of Celebrex® were and are adequately described in their FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Answering Defendants admit that during certain period(s) of time, Pfizer co-promoted and marketed the

prescription drug Celebrex® in the United State for the indications set forth in the FDA-approved package inserts and as permitted by law. Except as admitted herein, Answering Defendants deny the allegations contained in this Paragraph as they relate to Answering Defendants.

149. Answering Defendants deny that Celebrex® caused Plaintiff and/or decedent any harm and deny that Plaintiff is entitled to any damages. Answering Defendants deny the remaining allegations contained in this Paragraph as they relate to Answering Defendants.

ANSWERING:
COUNTY VII – WRONGFUL DEATH

150. Answering Defendants incorporate their responses to Paragraphs 1-149 as if set forth fully herein.

151. This Paragraph contains legal conclusions to which no response is required.

152. Answering Defendants state that Celebrex® was and is safe and effective when used in accordance with their FDA-approved prescribing information. Answering Defendants deny that Celebrex® caused Plaintiff and/or the decedent any harm. Except as admitted herein, Answering Defendants deny the allegations contained in this Paragraph as they relate to Answering Defendants.

153. Answering Defendants have insufficient information or knowledge to form a belief as to the truth of the allegations regarding Decedent's and Plaintiff's alleged incurred expenses and therefore deny the same. Answering Defendants deny that Celebrex® caused Plaintiff and/or the decedent any harm. Except as admitted herein, Answering Defendants deny the allegations contained in this Paragraph as they relate to Answering Defendants.

154. Answering Defendants deny the allegations contained in this Paragraph as they relate to Answering Defendants.

Answering Defendants also deny the demands set forth in this unnumbered WHEREFORE Paragraph of Plaintiff's Complaint.

ANSWERING:
COUNT VIII – CONSUMER PROTECTION ACT
(Against Merck and Pfizer)

155. Answering Defendants incorporate their responses to Paragraphs 1-154 as if set forth fully herein.

156. Answering Defendants state that Celebrex® was and is safe and effective when used in accordance with their FDA-approved prescribing information. Answering Defendants state that the potential effects of Celebrex® were and are adequately described in their FDA-approved prescribing information, which was at all times adequate and comported

with applicable standards of care and law. Answering Defendants deny making misrepresentations about the safety and effectiveness of Celebrex®. Except as admitted herein, Answering Defendants deny the allegations contained in this Paragraph as they relate to Answering Defendants.

157. Answering Defendants deny the allegations contained in this Paragraph as they relate to Answering Defendants.

158. Answering Defendants have insufficient information or knowledge to form a belief regarding Decedent's use of Celebrex® and therefore deny the same. Except as admitted herein, Answering Defendants deny the allegations contained in this Paragraph as they relate to Answering Defendants.

159. Answering Defendants have insufficient information or knowledge to form a belief as to the truth of the allegations regarding Decedent and therefore deny the same. Except as admitted herein, Answering Defendants deny the allegations contained in this Paragraph as they relate to Answering Defendants.

160. Answering Defendants deny that Celebrex® caused Plaintiff and/or decedent any harm and deny that Plaintiff is entitled to any damages. Answering Defendants deny the remaining allegations contained in this Paragraph as they relate to Answering Defendants.

161. Answering Defendants deny the allegations contained in this Paragraph as they relate to Answering Defendants.

ANSWERING:
COUNT IX
(Claims Against James A. Stewart, Anna Leigh Webb, Cedric D. Anderson, Travis Taylor and Robert Vandelune, Sales Representative Defendants)

162. Answering Defendants incorporate their responses to Paragraphs 1-161 as if set forth fully herein.

163. Answering Defendants have insufficient information or knowledge to form a belief as to the truth of the allegations contained in this Paragraph and therefore deny the same.

164. Answering Defendants admit that they have such duties as are imposed by applicable law, but deny that they breached any such duty. Except as admitted herein, Answering Defendants deny the allegations contained in this Paragraph as they relate to Answering Defendants.

165. Answering Defendants admit that they have such duties as are imposed by applicable law, but deny that they breached any such duty. Except as admitted herein, Answering Defendants deny the allegations contained in this Paragraph as they relate to Answering Defendants.

166. Answering Defendants deny the allegations contained in this Paragraph as they relate to Answering Defendants. Answering Defendants

state that Celebrex® was and is safe and effective when used in accordance with their FDA-approved prescribing information. Answering Defendants state that the potential effects of Celebrex® were and are adequately described in their FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law.

167. Answering Defendants deny the allegations contained in this Paragraph as they relate to Answering Defendants. Answering Defendants state that Celebrex® was and is safe and effective when used in accordance with their FDA-approved prescribing information. Answering Defendants state that the potential effects of Celebrex® were and are adequately described in their FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law.

168. Answering Defendants state that Celebrex® was and is safe and effective when used in accordance with their FDA-approved prescribing information. Answering Defendants deny that Celebrex® caused harm to Plaintiff, the decedent and others. Except as admitted herein, Answering Defendants deny the allegations contained in this Paragraph as they relate to Answering Defendants.

169. Answering Defendants state that Celebrex® was and is safe and effective when used in accordance with their FDA-approved prescribing

information. Except as admitted herein, Answering Defendants deny the allegations contained in this Paragraph as they relate to Answering Defendants.

170. Answering Defendants deny the allegations contained in this Paragraph as they relate to Answering Defendants.

171. Answering Defendants deny the allegations contained in this Paragraph as they relate to Answering Defendants.

172. Answering Defendants have insufficient information or knowledge to form a belief as to the truth of the allegations regarding Decedent's health care providers contained in this Paragraph and therefore deny the same. Answering Defendants deny the remaining allegations of this Paragraph as they relate to Answering Defendants.

173. Answering Defendants deny the allegations contained in this Paragraph as they relate to Answering Defendants.

174. Answering Defendants deny the allegations contained in this Paragraph, including all of its subparts, as they relate to Answering Defendants.

175. Answering Defendants are without sufficient information or knowledge regarding the identity of Decedent's health care providers and therefore cannot answer as to whether they visited Decedent's health care

providers. Answering Defendants deny the allegations contained in this Paragraph as they relate to Answering Defendants.

176. Answering Defendants are without sufficient information or knowledge regarding the identity of Decedent's health care providers and therefore cannot answer as to whether they visited Decedent's health care providers. Answering Defendants have insufficient information or knowledge to identify the "articles" referred to in this Paragraph. Answering Defendants state that the referenced studies speak for themselves and deny any characterization at them. Answering Defendants deny the allegations contained in this Paragraph, as they relate to Answering Defendants.

177. Answering Defendants state that Celebrex® was and is safe and effective when used in accordance with their FDA-approved prescribing information. Answering Defendants also state that the potential effects of Celebrex® were and are adequately described in their FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Except as admitted herein, Answering Defendants deny the allegations contained in this Paragraph as they relate to Answering Defendants.

178. Answering Defendants deny the allegations contained in this Paragraph, including all of its subparts, as they relate to Answering Defendants.

179. Answering Defendants have insufficient information or knowledge to form a belief as to the truth of the allegations contained in this Paragraph and therefore deny the same as they relate to Answering Defendants.

180. Answering Defendants have insufficient information or knowledge to form a belief as to the truth of the allegations contained in this Paragraph and therefore deny the same as they relate to Answering Defendants.

181. Answering Defendants have insufficient information or knowledge to form a belief as to any reliance by Decedent's health care providers as alleged in this Paragraph and therefore deny the same as they relate to Answering Defendants.

182. Answering Defendants state that this Paragraph contains legal conclusions to which no response is required. To the extent a response is deemed required, Answering Defendants admit that they have such duties as are imposed by applicable law, but deny that they breached any such duty. Answering Defendants also state that the potential effects of Celebrex® are

and were adequately described in their FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Except as admitted herein, Answering Defendants deny the allegations contained in this Paragraph as they relate to Answering Defendants.

183. Answering Defendants state that this Paragraph contains legal conclusions to which no response is required. To the extent a response is deemed required, Answering Defendants admit that they have such duties as are imposed by applicable law, but deny that they breached any such duty. Answering Defendants state that Celebrex® was and is safe and effective when used in accordance with their FDA-approved prescribing information. Except as admitted herein, Answering Defendants deny the allegations contained in this Paragraph as they relate to Answering Defendants.

184. Answering Defendants have insufficient information or knowledge to form a belief as to Decedent's health care providers as alleged in this Paragraph and therefore deny the same as they relate to Answering Defendants.

185. Answering Defendants state that this Paragraph contains legal conclusions to which no response is required. To the extent a response is deemed required, Answering Defendants admit that they have such duties as

are imposed by applicable law, but deny that they breached any such duty. Answering Defendants state that Celebrex® was and is safe and effective when used in accordance with their FDA-approved prescribing information. Answering Defendants also state that the potential effects of Celebrex® are and were adequately described in their FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Except as admitted herein, Answering Defendants deny the allegations contained in this Paragraph, including all of its subparts, as they relate to Answering Defendants.

186. Answering Defendants state that this Paragraph contains legal conclusions to which no response is required. To the extent a response is deemed required, Answering Defendants admit that they have such duties as are imposed by applicable law, but deny that they breached any such duty. Except as admitted herein, Answering Defendants deny the allegations contained in this Paragraph as they relate to Answering Defendants.

187. Answering Defendants deny the allegations contained in this Paragraph as they relate to Answering Defendants.

188. Answering Defendants deny the allegations contained in this Paragraph as they relate to Answering Defendants.

189. Answering Defendants deny the allegations contained in this Paragraph as they relate to Answering Defendants.

ANSWERING:
COUNT X – DAMAGES
(Against All Defendants)

190. Answering Defendants incorporate their responses to Paragraphs 1-189 as if set forth fully herein.

191. Answering Defendants deny the allegations contained in this Paragraph as they relate to Answering Defendants.

192. Answering Defendants deny the allegations contained in this Paragraph as they relate to Answering Defendants.

193. Answering Defendants deny the allegations contained in this Paragraph as they relate to Answering Defendants.

194. Answering Defendants deny the allegations contained in this Paragraph as they relate to Answering Defendants.

ANSWERING:
COUNT XI – PUNITIVE DAMAGES
(Against Merck and Pfizer)

195. Answering Defendants incorporate their responses to Paragraphs 1-194 as if set forth fully herein.

196. Answering Defendants state that this Paragraph contains legal conclusions to which no response is required. To the extent a response is

deemed required, Answering Defendants admit that they have such duties as are imposed by applicable law, but deny that they breached any such duty. Answering Defendants state that Celebrex® was and is safe and effective when used in accordance with their FDA-approved prescribing information. Answering Defendants also state that the potential effects of Celebrex® are and were adequately described in their FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Answering Defendants deny making misrepresentations regarding the safety and effectiveness of Celebrex®. Except as admitted herein, Answering Defendants deny the allegations contained in this Paragraph as they relate to Answering Defendants.

197. Answering Defendants state that this Paragraph contains legal conclusions to which no response is required. To the extent a response is deemed required, Answering Defendants admit that they have such duties as are imposed by applicable law, but deny that they breached any such duty. Answering Defendants state that Celebrex® was and is safe and effective when used in accordance with their FDA-approved prescribing information. Answering Defendants deny making misrepresentations regarding the safety and effectiveness of Celebrex®. Except as admitted herein, Answering

Defendants deny the allegations contained in this Paragraph as they relate to Answering Defendants.

198. Answering Defendants deny the allegations contained in this Paragraph as they relate to Answering Defendants.

199. Answering Defendants deny the allegations contained in this Paragraph as they relate to Answering Defendants.

ANSWERING:
COUNT XII – LOSS OF CONSORTIUM
(Against All Defendants)

200. Answering Defendants incorporate their responses to Paragraphs 1-199 as if set forth fully herein.

201. Answering Defendants deny the allegations contained in this Paragraph as they relate to Answering Defendants.

202. Answering Defendants deny the allegations contained in this Paragraph as they relate to Answering Defendants.

203. Answering Defendants deny the allegations contained in this Paragraph as they relate to Answering Defendants.

ANSWERING:
PRAYER FOR RELIEF

Answering Defendants deny that Plaintiff is entitled to any of the relief demanded in Plaintiff's Prayer for Relief clause, including its subparts.

DEFENSES

Discovery and investigation may reveal that any one or more of the following defenses should be available to Answering Defendants in this matter. Answering Defendants therefore assert the following defenses to preserve the right to assert them. Upon completion of discovery, and if the facts warrant, Answering Defendants will withdraw any of these defenses as may be appropriate. Answering Defendants also intend to rely upon such other affirmative defenses as may become available or apparent during the course of investigation, discovery, or trial, and reserves the right to amend the Answer to assert such other defenses to which they may be entitled.

1. Plaintiff's Complaint fails to state a claim against Answering Defendants upon which relief can be granted.

2. Plaintiff's claims are barred by the applicable statute of limitations and/or repose or by the equitable doctrines of laches, waiver and estoppel.

3. Plaintiff's injuries and damages, if any, were solely caused by the acts or omissions, abuse or misuse, negligence or fault or otherwise, of Plaintiff, third persons or parties over whom Answering Defendants have no control or right to control and whose actions are not, therefore, imputable to Answering Defendant.

4. Answering Defendants made no warranties of any kind, express or implied, or any representations of any nature whatsoever to Plaintiff or Decedent herein. Additionally, as a manufacturer and not a seller, Answering Defendants are not subject to liability for implied warranties without privity, i.e., proof of direct and specific transactions between Plaintiff or Decedent and Answering Defendants. If any such warranties were made, whether express or implied, which Answering Defendants specifically deny, then Plaintiff has failed to give timely notice of any breach thereof as required under Ala. Code § 7-2-607.

5. Plaintiff's injuries and damages, if any, were proximately caused by the negligence or fault of Plaintiff or Decedent or those acting at the direction or control of Plaintiff or Decedent, whose contributory negligence or fault are sufficient to bar any recovery by Plaintiff.

6. Plaintiff's injuries, if any, are due to an unforeseeable idiosyncratic reaction of Decedent, or by an unforeseeable disease or illness, unavoidable accident, or pre-existing and/or unrelated conditions, or natural courses of conditions of Decedent, and were independent of any conduct by Answering Defendants.

7. Plaintiff and Decedent failed to exercise reasonable care and diligence to mitigate their injuries and damages, if any.

8. Plaintiff's claims are barred or limited to a product liability failure to warn claim because Celebrex® is a prescription pharmaceutical drug and falls within the ambit of Restatement (second) of Torts § 402A, Comment k.

9. Celebrex® is safe when used as directed, is suitable for the purpose for which it was intended, was distributed with adequate and sufficient warnings and Answering Defendants reasonably assumed that their warnings would be read and heeded; therefore, Celebrex® was not defective or unreasonably dangerous pursuant to Restatement (Second) of Torts § 402A, Comment j.

10. As a prescription pharmaceutical, Celebrex® falls within the ambit of the Food, Drug and Cosmetic Act and regulations promulgated by the Food and Drug Administration. Accordingly, Plaintiff's claims have been preempted under the Supremacy Clause of the U.S. Constitution.

11. Celebrex® and Answering Defendants' actions, conformed to the state-of-the-art of medical and scientific knowledge at all times relevant to this lawsuit and Celebrex® complied with applicable product safety statutes and regulations as described in Restatement (Third) of Torts: Products Liability § 4.

12. Plaintiff's claims are barred by assumption of the risk.

13. Plaintiff's claims are barred in whole or in part because Celebrex® "provides net benefits for a class of patients" within the meaning of the Restatement (Third) of Torts: Product Liability § 6, Comment f.

14. Plaintiff's claims asserted in the Complaint are barred in whole or in part by the "learned intermediary" doctrine.

15. The imposition of punitive damages pursuant to current Alabama law violates the Due Process and Equal Protection provisions of U.S. Const. Amend. XIV; to wit, Answering Defendants have not been given fair notice of the standard of conduct which could subject it to a claim for punitive damages, and have not been given fair notice of the amount of punitive damages that may accompany a finding of liability. Alabama's current laws regarding punitive damages do not serve a rational or legitimate state interest.

16. Plaintiff's claims for punitive damages violate this Answering Defendant's rights under the Fifth, Sixth, Seventh, Eighth, and Fourteenth Amendment of the Constitution of the United States of America and Article 1, Sections 1, 2, 6, 11, 13, 15, 27, and 35 of the Constitution of Alabama.

17. Plaintiff's claims for punitive damages are limited or barred by the standards governing exemplary damages awards which arise under the United States Constitution and decisions of the United States Supreme Court

including, but not limited to: *BMW of North America v. Gore*, 116 U.S. 1589 (1996); *Cooper Industries, Inc. v. Leatherman Tool Group, Inc.*, 532 U.S. 424 (2001); and *State Farm Mut. Auto. Ins. Co. v. Campbell*, 538 U.S. 408 (2003). Further, Plaintiff's claims for punitive damages are limited or barred by the standards governing exemplary damages, which arise under the Constitution of Alabama, Alabama state statutes, and the decisions of Alabama state courts.

18. The methods, standards, and techniques utilized with respect to the manufacture, design, and marketing of Celebrex®, if any, used in this case, included adequate warnings and instructions with respect to the product's use in the package insert and other literature, and conformed to the generally recognized, reasonably available and reliable state of the knowledge at the time the product was marketed.

19. If Plaintiff sustained any injuries or incurred any losses or damages as alleged in the Complaint, the same was caused by operation of nature or other supervening or intervening conduct or negligence of persons other than Answering Defendants, and for whose conduct Answering Defendants are not responsible, or with whom Answering Defendants have no legal relation or legal duty to control. Therefore, Plaintiff's recovery against Answering Defendants, if any, should be reduced by the proportion

of the conduct or negligence of persons or entities other than Answering Defendants which proximately caused or contributed to the alleged injuries, losses or damages.

20. If Plaintiff sustained any injuries or incurred any losses or damages as alleged in the Complaint, the same was caused by the unforeseeable alterations, improper handling, or other unforeseeable misuse of Celebrex® by persons other than Answering Defendants or persons acting on its behalf.

21. Plaintiff's claims asserted in the Complaint are barred, in whole or in part, because Celebrex® did not proximately cause injuries or damages to Plaintiff.

22. To the extent that Plaintiff's claims are based on a theory providing for liability without proof of causation, the claims violate Answering Defendants' rights under the United States Constitution.

23. Plaintiff's claims asserted in the Complaint are barred, in whole or in part, because Plaintiff did not incur any ascertainable loss as a result of Answering Defendants' conduct.

24. Plaintiff's claims asserted in the Complaint are barred, in whole or in part, because the manufacturing, labeling, packaging, and any advertising of Celebrex® complied with applicable codes, standards and

regulations established, adopted, promulgated or approved by any applicable regulatory body, including but not limited to the United States, any state, and any agency thereof.

25. Plaintiff's claims are barred, in whole or in part, because the advertisements, if any, and labeling with respect to Celebrex® was not false or misleading and, therefore, constitute protected commercial speech under the applicable provisions of the United States Constitution.

26. Plaintiff's claims must be dismissed because Decedent would have taken Celebrex® even if the product labeling contained the information that Plaintiff contends should have been provided.

27. Plaintiff's claims asserted in the Complaint are barred because the utility of Celebrex® outweighed its respective risks.

28. Plaintiff's fraud-based claims, if any, are not stated with particularity as required by Rule 9 of the Federal Rules of Civil Procedure.

29. Plaintiff's damages, if any, are barred or limited by the payments received from collateral sources.

30. The liability of Answering Defendants, if any, can only be determined after the percentages of responsibility of all persons who caused or contributed toward Plaintiff's alleged damages, if any, are determined. Answering Defendants seek an adjudication of the percentage of fault of the

claimants *and* each *and* every other person whose fault could have contributed to the alleged injuries and damages, if any, of Plaintiff.

31. Answering Defendants are entitled to credit for any settlement of claims for alleged injuries and damages made by Plaintiff with any other person or entity.

32. Plaintiff's claims are preempted by federal law and regulations, including but not limited to the Federal Food, Drug & Cosmetic Act, 21 U.S.C. §301 et. seq., the regulations promulgated there under, and the United States Constitution, Article N, Clause 2.

33. Plaintiff's claims are barred, in whole or in part, by the doctrine of abstention in that the common law gives deference to discretionary actions by the United States Food and Drug Administration under the Federal Food, Drug and Cosmetic Act.

34. Plaintiff's claims asserted in the Complaint are barred, in whole or in part, by the doctrines of primary jurisdiction and exhaustion of administrative remedies, because the FDA has exclusive or primary jurisdiction over the matters asserted in the Complaint.

35. Plaintiff's claims asserted in the Complaint are barred, in whole or in part, because Celebrex® is comprehensively regulated by the FDA pursuant to the Federal Food, Drug & Cosmetic Act ("FDCA"), 21 U.S.C.

§301 et seq., and regulations promulgated there under, and Plaintiff's claims conflict with FDCA, with the regulations promulgated by FDA to implement the FDCA, with the purposes and objectives of the FDCA and FDA's implementing regulations, and with the specific determinations by FDA specifying the language that should be used in the labeling accompanying Celebrex®. Accordingly, Plaintiff's claims are preempted by the Supremacy Clause of the United States Constitution, Article VI, Clause 2, and laws of the United States.

36. If Plaintiff has sustained injuries or losses as alleged in the Complaint, upon information and belief, such injuries and losses were caused by the actions of persons not having real or apparent authority to take said actions on behalf of Answering Defendants and over whom Answering Defendants had no control and for whom Answering Defendants may not be held accountable.

37. Plaintiff's claims are barred, in whole or in part, by the doctrine of accord and satisfaction.

38. This Court lacks personal jurisdiction over Answering Defendants.

39. Plaintiff failed to join all indispensable parties; as a result of such failure to join, complete relief cannot be accorded to those already

parties to the action and will result in prejudice to Answering Defendants in any possible future litigation.

40. Any judicially-created definitions of manufacturing defect and design defect, and standards for determining whether there has been an actionable failure to warn, are unconstitutional in that, among other things, they are void for vagueness and an undue burden on interstate commerce, as well as an impermissible effort to regulate in an area that previously has been preempted by the federal government.

41. To the extent that Plaintiff seeks punitive damages for an alleged act or omission of Answering Defendants, no act or omission was oppressive, fraudulent, or malicious, and therefore, any award of punitive damages is barred.

42. Plaintiff's claims are barred, in whole or in part, because all acts or omissions by Answering Defendants (or their agents or representatives) were privileged or justified and any claim based thereon is barred.

JURY DEMAND

Answering Defendants demand a trial by jury on all issues so triable.

WHEREFORE, Answering Defendants respectfully request that this action be dismissed with prejudice and that they be awarded costs and any other forms of relief to which they may be entitled.

Dated this 2nd day of February, 2007.

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CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of the foregoing was filed via U.S. mail and the CM/ECF system on this 2nd day of February, 2007, to the following counsel of record:

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